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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,417	02/15/2007	Bakulesh Mafatlal Khamar	21059/0206951-US0	2043

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,417	KHAMAR, BAKULESH MAFATLAL	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 37-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 37-69 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 07 June 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/15/07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The specification should be amended to include the correct reference to the strain being used in the pharmaceutical composition, e.g., 'Mycobacterium w" should be used consistently throughout the specification. Additionally, the numerous misspellings throughout the specification from the translation should be corrected.

Appropriate correction is required.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-69 are vague and confusing because it is unclear what strain is being used in the claimed methods. The prior art refers to 'mycobacterium w' as 'Mycobacterium w'. It is suggested that the claims be amended to recite 'Mycobacterium w' or applicant's should provide further clarification.

Claim 37 is vague and indefinite because it is unclear what is encompassed by the phrase 'managing cancer'. How is the disease 'managed'? In what manner does the composition 'manage' the disease? Clarification and correction is requested.

Claim 37 (and 48-51) is also vague and indefinite because it is unclear what is encompassed by the phrase 'constituents of mycobacterium w'. What is the structure of the constituents? Are they proteins, DNA, carbohydrates, etc.? The mere recitation of the name, i.e., constituents, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties which would allow for one to identify the protein without ambiguity. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The methods recited in claims 48-51 are not specific enough to reproduce the same constituents such that one can determine what is being claimed for patent purposes. Clarification and correction is requested.

Claim 38 is vague and confusing because it is unclear what is meant by 'decreasing the burden of cancer tissue". Is this equivalent to stopping malignancy or something else? Clarification and correction is requested.

Claims 39 and 40 are vague and confusing because they don't appear to 'treat cancer' per se, but appear to be drawn to managing the effects of cancer therapy which is a different method then 'treating cancer'.

Claim 42 is vague and confusing because it is a method to 'avoid postponement of chemotherapy' yet it depends from a claim in which chemotherapy was performed. Clarification and correction is requested.

Claim 57 should be amended to get rid of the extra spacing in line 2 and the word 'hydrolyse' should be changed to 'hydrolyze'.

Claim 58 is vague and confusing because it is unclear what is encompassed by 'other modes of therapy'. These are method steps which are critical to the invention and should be recited in the claim.

Claim 65 is vague and confusing because it is unclear if the information in the parentheticals is intended to be part of the claim or not. Clarification and correction is requested.

Claim 66 is vague and indefinite due to the phrase 'quality of like'. This appears to be a typographical error and should be changed to 'quality of life'.

Claim 68 is vague and confusing because it is unclear what is encompassed by the phrase 'with the addition of other modes of treatment'. . While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. These additional steps are critical parts of the invention and should be included in the claim.

Claim 69 is vague and confusing because it is unclear what is encompassed by 'symptoms associated with cancer', particularly because the preceding claims mention

symptoms associated with treatment methods of cancer. It is unclear what symptoms are encompassed by the claims.

Claim Rejections - 35 USC § 112-Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention - The claims are drawn to methods of treating or managing cancer; improving the quality of life in a patient suffering from cancer; ameliorating symptoms associated with cancer comprising administration to a patient a pharmaceutical composition comprising an effective amount of Mycobacterium w or constituents of Mycobacterium w. It is later claimed that the composition may be prepared by cell disruption, solvent extraction, or enzymatic extraction.

The amount of direction/guidance/examples present -The instant specification in its present form, while reciting various preparations of Mycobacterium w, does not specify which of the types was actually utilized nor how much of the composition was administered in the recited Examples. Therefore, there is insufficient information to enable the instant claims. The required information to support the instant claims, at a

minimum, would be the actual composition administered to the patients (whole cells, disrupted cells, cell fractions, etc), the dosage administered, the route of administration, and the frequency of administration. The instant specification does recite 10 different preparations of Mycobacterium w pharmaceutical composition, i.e., heat killed whole cells, methanol extract, chloroform extract, sonicate, acetone extract, ethanol extract, and does not specify which of the types was actually utilized. Because of the wide variety of the composition preparations, the actual constituents in each of the pharmaceutical compositions also vary greatly. Thus, without knowing exactly which preparation was utilized, there is insufficient information to enable the instant claims which merely recite "a pharmaceutical composition comprising an effective amount of" either "Mycobacterium w" or "a" constituent of Mycobacterium w.

Cancer treatment is an extremely unpredictable art with a solid statistical data required to support it. The instant specification shows only anecdotal evidence of a few isolated patients with various symptoms and does not recite the actual composition used or the amount. These isolated, independent anecdotal examples are not sufficient to enable the claimed methods. The anecdotal case studies contain so many different variables and factors it is unclear what is actually causing the different effects and if they can be attributed to the Mycobacterium w composition. None of the isolated incidents are sufficient to support claims broadly drawn to method for treatment or management of any cancer, nor do they support a method for the amelioration of symptoms associated with any cancer or improvement in quality of life in a cancer patient.

Status of Claims:

No claims are allowed. The prior art has taught the *idea* of the use of Mycobacterium w in pharmaceutical compositions for treating leprosy and treating HIV; however, the prior art does not teach or suggest using a pharmaceutical composition of Mycobacterium w or its constitutents to treat or manage cancer, improve the quality of life in a patient with cancer or a method of ameliorating symptoms associated with cancer.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

12/18/08